UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Magistrate Judge Marianne B. Bowler

PLAINTIFFS' REPLY AND SURREPLY TO ROXANE'S CONSOLIDATED SUMMARY JUDGMENT MEMORANDUM

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"Abuse." "A nationwide problem." "A plot." "Inflated" price reporting that "cheat[s] taxpayers" as it leads to government "overpayments."[1] This is how various government reports referred to the manipulation by drug manufacturers of the Medicare/Medicaid reimbursement system through a practice of reporting inflated AWPs that were relied on as a basis for calculating reimbursement amounts. The Roxane defendants' selected quotations from government reports and officials do not show government *approval* of that practice. Rather, they demonstrate a developing realization, often only after painstaking and resource-intensive investigation, of the *distortion* of AWP through the defendants' abuse. There was no official approval of the way Roxane gamed the system, and Roxane does not point to any.

Absent from the Roxane defendants' Consolidated Opposition/ Reply Memorandum (Rox. Reply Brief) is any dispute about what Roxane itself actually told – or more importantly did not tell – federal and state officials: Roxane did not inform the government that it was reporting inflated AWPs that bore no predictable relation to cost or actual prices. Roxane did not disclose that Roxane itself, not the pricing compendia, set the AWPs that were published for its drugs. Roxane did not ever suggest, to any government official, that it was deliberately setting inflated AWPs in order to compensate for dispensing fees it or its customers considered inadequate. Nor did Roxane explain the real reason behind its method for setting its reported AWPs – to increase reimbursement for its products and thereby gain a competitive advantage.

Roxane now seeks to avoid liability through a *post hoc* argument that reports and testimony acquired after this litigation was instituted show that "everybody knew" AWPs were inflated, and so the government wasn't defrauded. Roxane's attempt to deflect attention from its conduct by shifting focus to what government officials were able to *uncover*, piecemeal, and to

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[1] *E.g.*, US Response to Roxane SOF, ¶¶ 2, 3, 29, 35, 40, 46, 54, 59, 63, 64.

the discussion about how to solve the problem Roxane and others created, fails. During the relevant period, Roxane had no reason to believe – and did not believe – that the government approved of its conduct. On the contrary, Roxane officials who set reported prices in order to maximize profit did not review *at the time* the OIG reports and statements Roxane now says show government endorsement. Nor did they rely on such reports as an indicator of government approval. Indeed, Roxane became aware the government was *investigatin*g (and by implication did not approve of) inflated AWPs. Nonetheless, as one Roxane official observed in August 2000, even though "big brother" was likely to catch up to and "punish" them, "why not make some money meanwhile?" *See* US-Rox-SOF, Master Docket ("MD") # 6207, Sub. # 261, ¶ 80.

Finally, Roxane provides no basis for entering summary judgment in its favor as to its marketing of NovaPlus® ipratropium bromide, since it marketed the product "under a name other than the generic chemical name," which fits CMS' published criteria for a "brand."

ARGUMENT

In response to defendants' "Combined Memorandum" in opposition to the United States' cross-motions for partial summary judgment (MD 6429), the United States is submitting a common reply memorandum of law in support of its cross-motions for partial summary judgment and sur-reply in opposition to the defendants' motions for summary judgment ("US Common Reply"), that addresses many of the same core arguments made in Roxane's Reply Brief, and that brief is incorporated herein by reference. The United States therefore addresses only a few discrete issues below.

A. Roxane's Smoke and Mirrors Cannot Obscure the Core Facts

As an initial matter, in their 25-page brief, the Roxane defendants do not run from the essential, material fact that their AWPs were falsely inflated to create an artificial spread for the

sole purpose of promoting sales. Roxane knew that customers cared about the spread because it enabled those customers to obtain larger reimbursement payments, and when Roxane initially set its AWPs "to be competitive," or raised AWPs years after launching a drug, the *only* reason was to be able to sell more drugs based on a bigger spread.

Because it cannot deny those facts, Roxane tries to shift the Court's attention elsewhere. Roxane claims that "the government knew" all along yet, by this litigation, seeks to create "after-the-fact" or "retroactive" falsity.[2] Rox. Reply Brief at 2, 3, 5-6, 23-24. Roxane hopes its repeated invocation of the "perfect storm of information" will lead the Court to conclude that, at minimum, knowledge negates falsity, if not also scienter. The Court should not be fooled. Knowledge that some or even many AWPs were inflated does not translate into approval of Roxane's practice of reporting prices entirely unmoored from reality. Roxane's price reporting was a deliberate, profit-driven fiction. The prices were false at the time they were reported, and the government never gave a green light to Roxane to report made-up AWPs and WACs.

Roxane's collection of statements by state and federal officials notwithstanding, the fact remains that as more information was uncovered about the defendants' practices, government frustration and condemnation became more heated. *See, e.g.*, U.S. Common SOF (MD 6316), ¶ 19, Henderson Common Exhibit 9, *Medicare Payments for Currently Covered Prescription Drugs: Hearing Before the Subcomm. On Health of the H. Comm. On Ways and Means*, 107th Cong. 7 (2002) (comments by Rep. Stark that pharmaceutical companies' "illegal behavior" was an "outrage" that "harms each and every one of us."). In any event, it is only formal, public agency statements that matter – not after-the-fact descriptions by individuals based on

[2]Roxane even quotes this Court's statement from a hearing on November 5, 2007, that "the government knew," *id.* at 23, but omits the Court's later observation that "knowledge is different from approval." *In re AWP Litig.*, C.A. No. 01-12257-PBS, Mot. Hr'g., 11/5/07 at 47.

observations and anecdotal evidence. As discussed in greater detail in the United States' Common Reply, under *United States v. Lachman*, informal, nonpublic understandings of agency officials concerning the meaning of regulations are not relevant to interpreting regulations. 387 F.3d 42, 54-55 (1st Cir. 2004). Accordingly, the statements and testimony by former and present agency officials cited by Roxane simply do not negate falsity. This is in part the case in this context because, as the First Circuit observed in *United States v. Michael Schiavone & Sons, Inc*., "it is not true that once a government agency smells a rat, the agency must exterminate it forthwith." 430 F.2d 231, 233 (1st Cir. 1970).

Second, Roxane zeroes in on very specific details about alleged anomalies in how Medicare determined allowed reimbursement amounts. Roxane argues, for instance, that three DMERCs violated CMS regulations when they omitted Zenith Goldline AWPs in pricing arrays for ipratropium bromide, and so there is no causation or scienter. Rox. Reply Brief at 19-20. Roxane is wrong. Having deliberately inflated its reported AWPs and profited from its manipulation of the reimbursement system, Roxane is not entitled to rely on alleged anomalies in how the DMERCs' determined allowed amounts as a way to escape liability. That the DMERCs would not update their pricing arrays with perfect synchronicity was certainly foreseeable to Roxane, and the inflated AWPs reported by Roxane undoubtedly were a substantial factor in causing the harm to the Medicare program. *See* Restatement (Second) of Torts § 435(2) (1965) (If an "actor's conduct is a substantial factor in bringing about harm to another, the fact that the actor neither foresaw not should have foreseen the extent of the harm or the manner in which it occurred does not prevent him from being liable"); *Gallick v. Baltimore and Ohio Railroad Company*, 372 U.S. 108, 120 (1963) ("[A]ssuming the existence of a threshold tort ... whatever damages flow from it are recoverable"); *Figueroa-Torres v. Toledo-Davila*, 232 F.3d 270, 275

(1st Cir. 2000) (noting that "an offender 'takes his victim as he finds him'") (*quoting United States v. Feola*, 420 U.S. 671, 685 (1975)). In any event, the reasonable decision to exclude products with singular features that would have inflated the mean was not inconsistent with CMS's interpretation of 42 C.F.R. § 405.517(c). Indeed, CMS ratified exactly that approach in its on-line claims processing manual. *See* Declaration of George B. Henderson, II, Submitting Common Exhibits In Support of Motions for Partial Summary Judgment, Exhibit 3 (Helton Declaration), ¶ 10.

B. Roxane's Argument That It Cannot be Liable Without a Statutory, Regulatory, or Contractual Authority Requiring AWPs to be Truthful is Simply Wrong

Roxane posits a novel argument: it cannot be liable under the False Claims Act unless defendants were expressly "required" to report honest AWPs that reflected actual acquisition costs. Rox. Reply Brief at 3-5, 7-10. Specifically, Roxane argues that it cannot be shown to have "knowingly or recklessly disregarded a nonexistent rule." *Id.* at 8. That argument is nonsense; one certainly can act with the requisite scienter in the absence of an express prohibition.[3] Roxane's argument is tantamount to a contention that there must be "actual knowledge" for FCA liability, when the statute expressly provides for deliberate ignorance and reckless disregard. 31 U.S.C. § 3729(b). Moreover, as this Court recognized in another AWP case, "defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program," *Massachusetts v. Mylan Labs*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008). They were therefore required to know that AWPs and WACs were used to calculate reimbursement, specifically that they were used by states to calculate Estimated Acquisition Cost ("EAC"), and that EAC was defined as the

[3]The term "false or fraudulent" is not defined in the FCA; under Roxane's argument, defendants should be completely off the hook for that reason alone.

Medicaid agencies' "best estimate of the price generally and currently paid by providers." *Id.* In light of that, "a jury could certainly conclude that the defendants . . . were . . . meant to report a price suitable for such estimation, that is, *a real price.*" *Id.*

In support of its contention that it cannot have knowingly violated "a nonexistent rule," Roxane cites *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742 (N.D. Tex. 2003). *Medica-Rents*, however, does not stand for the proposition that there must be express governing authority in order to find knowing falsity. At issue in *Medica-Rents* was whether defendants knowingly submitted false claims for an "overlay" mattress using the more lucrative code for "alternating pressure" mattresses. The court concluded they did not, in part because the "overwhelming evidence" showed there was "considerable confusion" about what could be billed under the code, defendants believed it was appropriate, they "repeatedly sought direction on how to bill," and had been instructed to use the code. *Id.* at 771, 773. The decision has no applicability here, where Roxane decidedly did *not* seek or rely on direction in reporting inflated AWPs.[4] Indeed, undisputed evidence, including testimony of its own witnesses, shows that when Roxane employees set AWPs, they consulted only the market. They were oblivious to the OIG reports that Roxane now invokes for government knowledge. Roxane officials in fact became aware that the government was investigating and *disapproved* of inflating AWPs.

C. Roxane is not Entitled to Summary Judgment for Claims Based on Its Marketing of NovaPlus® Ipratropium Bromide

Roxane's arguments concerning the United States' claims for damages resulting from

[4] In its recent affirmance, the Fifth Circuit specifically noted that the acting regional DMERC gave an express directive to Medica-Rents to use the code. *U.S. v. Medica-Rents CO. Ltd.*, 2008 WL 3876307 (5th Cir. August 19, 2008). Unlike in *United States ex rel. K&R Ltd. P'ship v. Mass. Housing Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008), which Roxane also cites, the United Sates points to plenty that would warn Roxane away from any view that its conduct was appropriate. Roxane's reliance on *Safeco. Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007), is also misplaced, since *Safeco* deals with a specific statutory requirement – exactly what Roxane argues is absent here.

inclusion in Medicare pricing arrays of Roxane's NovaPlus® Ipratropium Bromide as a brand rather than generic drug, Rox. Reply Brief at 11-19, repeat the mistaken premise of its initial argument: that the drug was "misclassified" by the DMERCs. A "brand" drug includes any product marketed, as Roxane's NovaPlus® Ipratropium Bromide was, under "a proprietary name." 63 Fed Reg. 58,814, 58,849-50. The relevant CMS regulation, 42 C.F.R. § 405.517(c), clarified that "[a] 'brand' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological." 63 Fed. Reg. 58,814, 58,849 (Nov. 2, 1998). It is undisputed that Roxane marketed the product not simply as ipratropium bromide, but as NovaPlus® Ipratropium Bromide. It was therefore correctly classified as a brand by three of the four DMERCs.

Roxane insists that "DOJ's" interpretation of this regulation is "strained and formalistic," Rox. Reply Brief at 12, and, without support, claims that the regulation "focuses on" the "absence" of the generic chemical name. *Id.* at 13. On the contrary. It is Roxane that grasps at a strained interpretation: marketing a product as a brand "rather than" a generic does not mean the generic name is "absent." *Adding* the NovaPlus® brand to the label on some of Roxane's ipratropium bromide products leads to marketing the drug as something "other than" the generic, just as Kleenex® and Coors® are marketed as brands, even though they also include the generic term "tissue" or "beer." The NovaPlus® name presumably was added for a reason, to distinguish the product, and Roxane's own marketing materials *did* distinguish between its generic "Ipratropium Bromide Inhalation, 0.02%" and the one marketed with the NovaPlus® brand. U.S. Resp. to Rox SOF, ¶¶ 141, 142.

Despite general protestations by Roxane that two additional DMERC affidavits submitted in opposition to Roxane's Motion for Summary Judgment present "new" arguments, Roxane has

not shown that the affidavits contradict any specific prior testimony. Nor does it matter as to Roxane's liability whether the DMERCs "uniformly" classified every NovaPlus® product as a brand, every time. The relevant question is whether the classification of NovaPlus® Ipratropium Bromide was correct. Under the published regulation and guidance it was.

CONCLUSION

As demonstrated above, in the United States' Consolidated Memorandum of Law (MD 6291, Subcategory # 298-3), and in the United States' Reply Brief filed herewith, Roxane is not entitled to summary judgment on any point, and its motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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Dated: 22 September 2009